Standards for Clinical Research and Pharmaceutical Product Development

PROPOSAL

Use of HL7 as Forum and Methodology to Provide Technical Specification of ICH Electronic Messages and Structured Documents

Contents

- Action proposed
- Perceived problem
- Background
- Benefits

Contents

- **Action proposed**
- Perceived problem
- Background
- Benefits

Action Proposed

- ICH should use Health Level Seven (HL7) methodology to create and maintain technical specifications for data interchange messages and structured documents.
- Requirements for reports and submissions should be provided to the appropriate HL7 technical committee (in most cases this will be the Regulated Clinical Research Information Management or RCRIM TC) as guidelines for reports, documents or submissions are defined.
- Technical experts from the ICH community including the M2 Expert Working Group should participate in HL7 Working Group meetings and in the development of technical specifications.
- HL7 RCRIM representatives should participate as observers in the M2 EWG.

Contents

- Action proposed
- **Perceived problem**
- Background
- Benefits

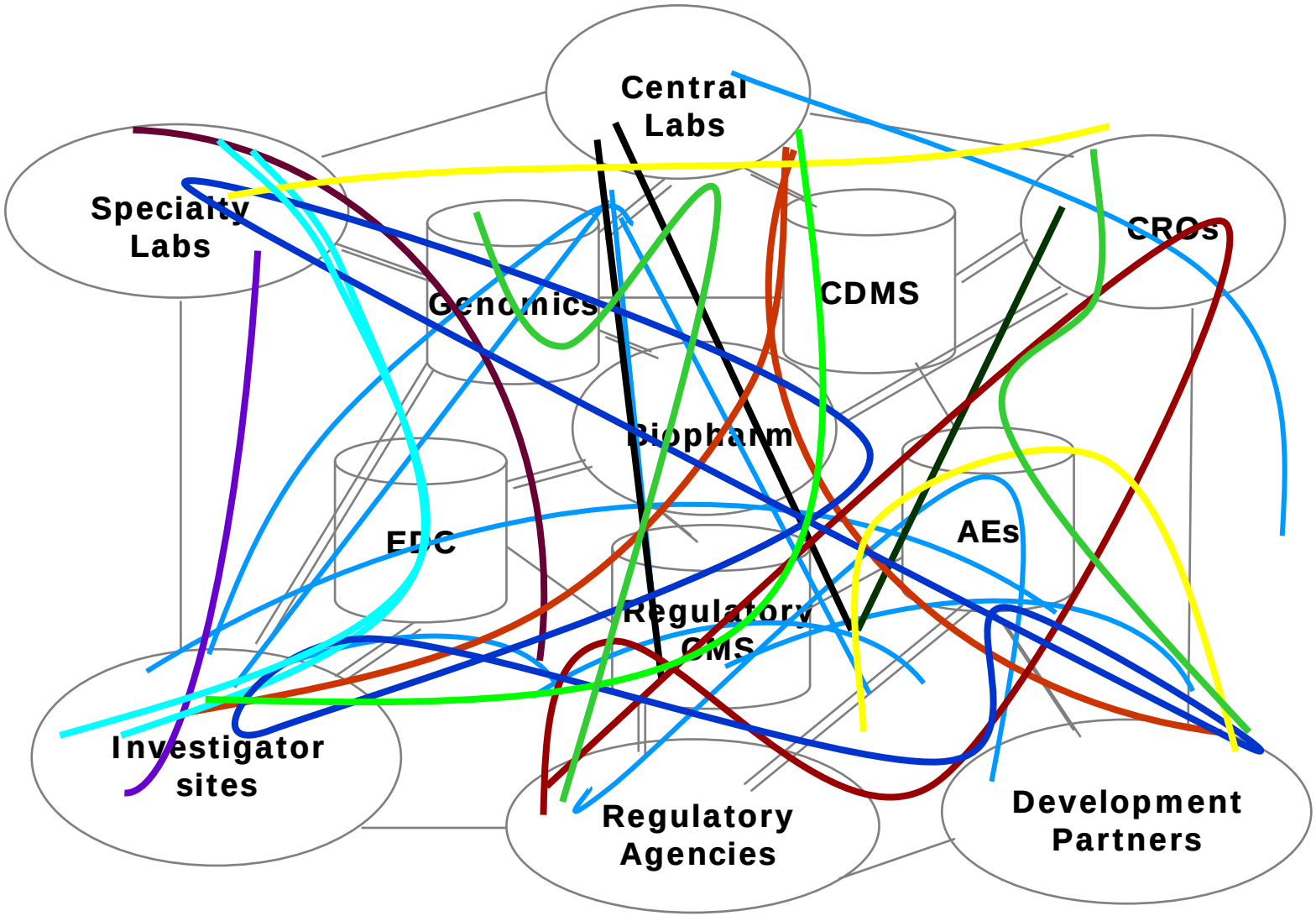
Perceived Problem

- Standards are means to desirable end
  - **Goal**: Improved time to market for safe and effective treatments (increased patient safety and reduced costs)
  - **Strategy**: More efficient choreography of large number of data interchanges from many sources that occur over a long period of time in clinical research and regulatory evaluation
  - **Tactic**: Use of standards to enable efficient transfer data in a reliable, secure manner and in a way that specifies what data is being transferred (so processing can be automated)

Efficient Data Transfers and Reuse Are Critical

- Drug Development is a Complex Business System
  - Processes cross functional and organizational boundaries
  - Lots of stakeholders and users of information with varying agendas
  - Information exchanges play important role in connecting activities and maintaining relationships

Drug Development is a Complex Business System



Elements of Perceived Problem

- Messages and structured document standards created by ICH are usually not in alignment with already established regional or international standards. This leads to several limitations.
  - Technical specifications developed by ICH therefore are very different from interchange standards used by other organizations and that are widely supported by technology used across the clinical research, life science, and healthcare industry.
  - ICH organizations have limited ability use and reuse electronic data acquired, maintained or received by computer systems other than those developed specifically to deliver ICH requirements.
  - Data in messages and structured documents developed to support one guideline may not be easily reused in a report or submission defined by a different guideline.

Elements of Perceived Problem

- Participation in the creation of technical specifications is limited to representatives from pharmaceutical organizations and regulators from the United States, Europe and Japan.
  - ICH does not have the advantage of broad and relevant expertise and must pull from a very limit resource pool.
  - Health care and solution providers, who often have a great deal of experience with creating and implementing technical standards, are not included.
  - Outside technical experts (data modelers, architects, systems analysts) do not participate in the process unless specifically invited.
  - Even for participant organizations, such as the FDA, representation is limited to a subset of key stakeholders.

Perceived Problem

- Under the current model, regulatory authorities and pharmaceutical companies that receive and transmit messages and structured documents based on both HL7 and ICH standards must invest in systems that are able to accommodate and support translation between formats.
  - Greater business value would be gained if required resources could be invested elsewhere.
  - Limited market slows the development and availability of new and additional technologies.
  - Standardizing to common reference information model and incorporating relationships between data components across a domain of interest into the standards and eliminates the need for this activity.

Perceived Problem

- ICH can benefit from taking advantage of an important resource.
  - HL7 is an international standards development organization that is specifically dedicated the definition of messages, document structures, and terminology needed to support the systems and processes used in the collection, storage, distribution, integration and analysis of research and healthcare information.
  - HL7 standards are developed according to a defined, accredited methodology and are founded in a common information model that is referenced by all domains of interest. The HL7 information model ensures that standards are interoperable—that data received by one computer system other can be exchanged and used by any computer system that is compliant with the standard.

Contents

- Action proposed
- Perceived problem
- **Background**
- Benefits

Background

- HL7 is an accredited international standards development organization.
  - Founded in 1987, not-for-profit organization.
  - Scope involves both research and healthcare.
  - Uses a defined, formal methodology to develop and approve standards. Operating procedures designed to ensure consensus, openness and balance of interest.
  - Open to all interested participants and able to tap into extensive expertise and resources.
  - Formal relationships with a number of other standards setting organizations (e.g. CDISC, DICOM) that use HL7 processes for creating and maintaining messages.
  - Members are organized into technical committees (TCs) and special interest groups (SIGs).

Background

- TCs are directly responsible for the content of Standards.
  - Regulated Clinical Research Information Management (RCRIM) TC focuses in standards needed to improve or enhance information management during research and regulatory evaluation of the safety and efficacy of therapeutic products or procedures worldwide.
  - RCRIM participation includes international regulatory agencies, other government agencies, pharma, CDISC, academic research organizations, vendors, and service providers who operate in pharma market.
  - RCRIM defines messages, document structures, and terminology to support the systems and processes used in the collection, storage, distribution, integration and analysis of clinical research and drug development information.
  - Standards are developed to conform to business requirements and data and information needs of regulatory authorities and pharma industry AND the HL7 reference information model.

Contents

- Action proposed
- Perceived problem
- Background
- **Benefits**

Benefits

- ICH's is able to focus on advancing human pharmaceutical drug products.
  - Taking advantage of HL7 resources and expertise for development of technical specifications allows ICH to focus on the human pharmaceutical industry while ensuring that regulatory data standards are harmonized with healthcare standards.
  - Using HL7 for this purpose does not interfere with the autonomy of ICH and the ICH process for requirement gathering and specification.

Benefits

- ICH gains standards that meet their business requirements and that are robust are widely supported throughout the industry.
  - ICH would continue to specify the requirements for data and structured document interchanges between pharmaceutical companies and regulatory authorities
  - HL7 is international organization with extensive international membership and participation.
  - Technical standard would be based on collective input of industry experts. Number of organizations involved means that it is difficult for one group to dominate.
  - Balloting process requires the Technical Committee to address and resolve all negative ballots and comments.